REMARKS/ARGUMENTS

With this amendment, claims 3, 4, 6 and 56-62 are pending. Claims 1-2, 5, 7-11, and 12-55 are cancelled. New claims 59-62 are added. For convenience, the Examiner's rejections are addressed in the order presented in a March 31, 2006, Office Action.

I. Status of the claims

Claim 3 is amended to recite an ADNF III nucleic acid having a nucleic acid sequence comprising a complementary sequence of SEQ ID NO:2. Support for this amendment is found throughout the specification, for example, at page 5, lines 29 through page 6, line 3. Claim 3 is also amended to recite that the encoded ADNF III polypeptide exhibits neuroprotective action on a neuron cell and has a specific structural formula recited in the claim. Support for these amendments is found throughout the specification, for example, at page 14, line 30 through page 15, line 1; page 7, lines 2-26; and page 57 line 20 through page 59, line 11. These amendments add no new matter.

Claim 57 is amended to recite an isolated host cell. Support for this amendment is found throughout the specification, for example, at page 17, lines 20-22. This amendment is not a limiting amendment and adds no new matter.

New claims 59-62 are added and recite specific encoded ADNF III protein sequences. Support for this amendment is found throughout the specification, for example, at original claims 25-30. This amendment adds no new matter.

II. Objections to the specification

The Examiner requested amendment of the specification to update the relationships and status of the priority documents. Applicants have amended the first paragraph of the specification in response.

III. Rejections under 35 U.S.C. §112, first paragraph, written description and enablement

Claims 3-4, 6, and 56-58 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to describe the invention in a manner to convey that the inventors had possession of the invention at the time of filing. The description of the invention in the specification also allegedly fails to enable those of skill to make and use the invention. The Office Action states that the rejection encompasses both the written description and enablement requirements. To the extent the rejection applies to the amended claims, Applicants respectfully traverse.

Claim 57 allegedly embraces new matter because it recites "a host cell". In order to expedite prosecution, claim 57 is amended to recite "an isolated host cell". Claim 3 is rejected for reciting an "ADNF III gene". In order to expedite prosecution, claim 3 is amended to recite "an ADNF III nucleic acid".

Claim 3 and dependent claims are rejected because, allegedly, the ADNF III polypeptides encoded by the claimed nucleic acids are described so broadly that those of skill could not determine what structure or function the polypeptides must possess. The Office Action cited *Ex parte Maizel* 27 USPQ2d 1662, 1665 (BPAI 1992) as holding that claims drawn to DNA sequences encoding biologically equivalent proteins, without a defined amino acid sequence, are not enabled by disclosure of a single DNA sequence in the specification. Applicants respectfully assert that Maizel is properly construed as holding that a claim to a nucleic acid molecule limited by either structural characteristics of the encoded protein **or** by the function of the encoded protein is overly broad. As amended, the present claims are not overly broad and meet the requirements for enablement set forth in Maizel by reciting structural **and** functional characteristics of the encoded proteins.

The claims are now directed to a nucleic acid that hybridizes to a reference sequence and that encodes an ANDF III polypeptide that comprises the ADNF III core active site **and** has neuroprotective properties. The specification provides disclosure and examples of how to identify ADNF III polypeptides that comprise the ADNF III core active site and that have neuroprotective properties. No fewer than four assays for ADNF III polypeptides with

neuroprotective properties are disclosed in the specification, *e.g.*, at page 29, lines 9-16; page 35, lines 12-24; page 35, line 25 through page 36, line 5; and page 57, line 20 through page 63, line 23. The identification of ADNF III polypeptides with neuroprotective properties is exemplified at page 84, line 18 through page 87, line 14 and at Figures 6A-C, 7A-B, 8, and 10.

Moreover, according to the MPEP, claims directed to purified and isolated DNA species encoding a specifically named protein with a specifically identified sequence are enabled because one of skill could readily determine any one of the claimed embodiments. MPEP at §2164.08. Here, the encoded protein is an ADNF III core active site, *e.g.*, SEQ ID NO:6, or ADNF III polypeptide that comprises an ADNF III core active site, *e.g.*, SEQ ID NO:3, 10, 33, 34, 35, 55, 57, or 59. Thus, based on the disclosure of the specification and the examples, the claim scope is not broader than the supporting disclosure and those of skill are enabled to make and use the entire scope of the claimed invention.

According to the Office Action, the specification lacks sufficient description to convey to those of skill that the inventors were in possession of the invention of claim 3 and its dependent claims. To the extent the rejection for alleged lack of written description applies to the amended claims, Applicants respectfully traverse.

Applicants respectfully traverse the rejection. As currently applied, the specification does comply with US patent law for description of a nucleic acid or amino acid sequence. The Federal Circuit court of Appeals addressed the description adequate to show one of skill that the inventors were in possession of a claimed genus at the time of filing. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002). An applicant may also show that an invention is complete by

> . . . disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Id.* at 1613.

Furthermore, "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." *See, e.g.*, 66 Fed. Reg. 1099, 1106 (2001). "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). M.P.E.P. 2163.

The amended claims now provide both structural and functional limitations for the ADNF III polypeptides encoded by the claimed nucleic acids. The structure of the genus of polypeptides is recited as a formula, SEQ ID NO:10, in keeping with the Federal Circuit decision of *Lilly*. The formula recites the sequence of the encoded ADNF III core active site, *i.e.*, SEQ ID NO:6, which is required for functional activity. The encoded polypeptides must also exhibit neuroprotection of neuron cells. Assays for neuroprotective activity are found throughout the specification, for example at page29, lines 9-16; page 35, lines 12-24; page 35, line 25 through page 36, line 5; page 57, line 20 through page 63, line 23; page 84, line 18 through page 87, line 14 and at Figures 6A-C, 7A-B, 8, and 10. Based on this disclosure, those of skill would be able both to envision the structure of the claimed nucleic acids that encode the ADNF III polypeptides and to assay the polypeptides for the neuroprotective activity required by the amended claims. Thus, the specification provides written description for the amended claims.

In view of the above amendments and remarks, withdrawal of the rejections under 35 U.S.C. §112, first paragraph is respectfully requested.

IV. Rejections under 35 U.S.C. §112, second paragraph

Claim 6 is rejected as allegedly indefinite. In order to expedite prosecution, claim 6 is amended to recite "an ADNF III polypeptide", rather than "an ADNF polypeptide". In view of this amendment, withdrawal of the rejection for alleged indefiniteness is respectfully requested.

V. Rejections under 35 U.S.C. §102(a)

Claim 3 is rejected as allegedly anticipated by Nagase *et al. DNA Res.* 5:277-286 (1998). The rejection appears to apply because claim 3 recites SEQ ID NO:56 and 58. According to the Office Action, because claim 3 recites SEQ ID NO:56 and 58, claim 3 is not entitled to the benefit of the earliest filed priority document, U.S. Provisional Application No. 60/037,404, filed February 7, 1997. The Office Action has awarded claim 3 and dependent claims the benefit of the filing date of the parent application, Application No. 09/187,330, filed on November 6, 1998. Although the other disclosed ADNF III sequences are awarded the February 7, 1997 priority date, Applicants respectfully traverse the rejection of claims 3-4, 6, and 56-58 based on the recitation of SEQ ID NO:56 and 58. Nagase *et al.* is not prior art to any of the claimed sequences.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found…in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, in order to anticipate, the cited references must contain every element of the claims at issue. Nagase *et al.* does not disclose all of the elements of the claims and is not an enabled reference. Moreover, GenBank Accession No. AB018327, cited by Nagase *et al.* for sequence information, is not prior art because it was not available to the public before the November 6, 1998 filing date.

Nagase *et al.* recites a publication date of October 30, 1998. Applicants do not concede that that Nagase *et al.* was first made available to the public on or before this alleged publication date. Nagase *et al.* discloses generation of a size-fractionated human brain cDNA library, followed by screening for in vitro protein-coding potential, and then sequencing of the cDNA. Nagase *et al.* discloses physical maps of the clones, chromosomal locations, cDNA lengths and accession numbers that allegedly can be used to access the complete sequence data of the clones. However, Nagase *et al.* does not disclose the complete DNA sequence of any human brain cDNA library clone, including the clone alleged to anticipate the claims. Without such sequence information, Nagase *et al.* cannot enable one of skill to make and use any specific nucleic acid sequence.

The Federal Circuit has repeatedly ruled that in order to anticipate an invention, a prior art reference must contain an "enabling disclosure." *In re Hoeksema*, 158 USPQ 596, 600 (CCPA 1968). The proper test of an enabling description in a publication cited under §102 is:

> whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought. *Id.,* and *In re LeGrice*, 301 F.2d 929, 939 (C.C.P.A. 1962).

The claimed invention is a genus of ADNF III nucleic acid sequences, *i.e.,* chemical compounds. Courts have developed a body of case law regarding the information required to provide an enabling disclosure of a chemical compound. In order to place a chemical compound in possession of the public, the disclosure must be such that one of ordinary skill in the art could at once envisage the compound. *In re Donohue,* 207 USPQ 196, 199 (Fed Cir. 1980) and *In re Petering,* 133 USPQ 275, 279-280 (C.C.P.A. 1962). In addition, the reference must disclose a method of making the compound. *In re Hoeksema*, 158 USPQ at 601.

First, Nagase *et al.* fails to enable the claimed inventions because it does not provide a method of making the claimed ADNF III nucleic acids. The Federal Circuit has repeatedly ruled that general cloning methods, such as the library construction methods disclosed in Nagase *et al.*, are not sufficient to describe how to make a *specific* DNA sequence, such as a ADNF III nucleic acid of SEQ ID NOs:54-56. The Federal Circuit has provided a legal standard for information necessary to conceive a method of making a nucleic acid and, by analogy, the information necessary to disclose a method of making a nucleic acid. According to the Federal Circuit, both conception of a nucleic acid structure and a method of making a nucleic acid occur simultaneously with disclosure of the DNA sequence. *See Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); and *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). Thus, in order to disclose a method of making a *specific* nucleic acid or genus of nucleic acids, a *specific* DNA sequence must be provided. Without disclosure of the specific nucleic acid sequence, the cited reference does not provide the required "enabling disclosure."

Nagase *et al.* also fails to disclose the specific ADNF III nucleic acid sequences in a manner to allow one of skill to "at once envisage" SEQ ID NO's:54-59. Nagase *et al.* appears to rely on the disclosure of GenBank Accession No. AB018327 for the complete sequence of the nucleic acid. However, GenBank Accession No. AB018327 was submitted to public database after November 6, 1998, the earliest priority date for SEQ ID NO:56 and 58. As evidence of the first public availability date of the alleged anticipatory sequences, Applicants provide as Exhibit A, a revision history from the website of the National Center for Biotechnology Information for AB018327. AB018327 was first seen at the NCBI website on November 16, 1998, *i.e.*, after the November 9, 1998 filing date. Thus, neither Nagase *et al.* nor GenBank Accession No. AB018327 can be cited as prior art for the claimed invention, including SEQ ID NO's:54-59.

In view of the above amendments and remarks, withdrawal of the rejections for alleged anticipation is respectfully requested.

VI. Rejections under 35 U.S.C. §103(a)

Claims 56-58 are as allegedly obvious in view of Nagase *et al.* As discussed above, Nagase *et al.* is not properly cited as prior art. Nagase *et al.* is not an enabling reference and a supporting reference, Genbank accession no. AB018327, was not publicly available before the alleged priority date. In view of the above amendments and remarks, withdrawal of the rejections for alleged obviousness is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

/Beth L. Kelly/

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Attachments
BLK:blk
60807613 v1

NCBI

Sequence Revision History

Revision history for AB018327

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3882288	1	Jun 19 1999 4:27 PM	Dead	○	◉
3882288	1	Mar 17 1999 5:54 PM	Dead	○	○
3882288	1	Nov 16 1998 10:36 PM	Dead	○	○

Accession AB018327 was first seen at NCBI on Nov 16 1998 10:36 PM

EXHIBIT A

☐ **1:** AB018327. Reports Homo sapiens mRNA...[gi:3882288] Links

Features Sequence

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REFERENCE   1  (sites)
  AUTHORS   Nagase,T., Ishikawa,K., Suyama,M., Kikuno,R., Miyajima,N.,
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  TITLE     Prediction of the coding sequences of unidentified human genes. XI.
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  JOURNAL   DNA Res. 5, 277-286 (1998)
REFERENCE   2  (bases 1 to 4282)
  AUTHORS   Ohara,O., Suyama,M., Nagase,T., Ishikawa,K. and Kikuno,R.
  TITLE     Direct Submission
  JOURNAL   Submitted (08-OCT-1998) Osamu Ohara, Kazusa DNA Research Institute,
            Laboratory of DNA Technology; Yana 1532-3, Kisarazu, Chiba
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